

RESOLVE

Establishment of Electronic Reporting; Electronic Records

October 29, 2001

Tapes 1 through 5

*[To improve the succinctness of these transcripts, the facilitator's comments have been minimized or deleted. Comments by hearing participants that were inaudible or not specifically about the subject matter have also been deleted. Minor edits have been made to improve readability. Raw transcripts are available from RESOLVE upon request.]*

**Robin Roberts:** Welcome to this informal public hearing on the proposed establishment of the Electronic Reporting and Record-keeping Rule. I'm Robin Roberts, a mediator with RESOLVE. I'm not an employee of EPA nor do I advocate for any of their policies. I'm here to ensure that the agenda is honored and that we keep to the times of the topics indicated on the agenda...

The purpose of this informal public hearing is to provide you, the interested public, with an opportunity to supplement your formal written comments to EPA with oral comments and to seek clarification where needed on the rule. The proposed electronic reporting and records rule was published on August

31. The formal public comment period ends November 29 and written comments must be submitted to the docket by that time.

Instructions for submitting comments are included in the preamble of the rule. The informal hearing is not intended in lieu of submitting formal written comments. Nonetheless, this hearing is being recorded and a transcript of this hearing will be added to the docket.

Just as a point of logistics...

On the panel, I'd like to introduce Joe Retzer, Director of the Collections Services Division, Michael LeDesma of the Office of General Counsel and also part of the Electronic Reporting and Recordkeeping Rule Workgroup at EPA, and David Schwarz, co-chair for the workgroup, and Evi Huffer, also co-chair of the workgroup.

Before we head into this, I'd just like to have you all pull out your agendas and take a look... Female Participant: The preamble areas that we've listed are basically the main areas where you'll find that topic. However, we'll take any questions, any comments that you have on anything.

If you do have a comment, I'll have to ask that you come down here...

Ground rules...

So, with no further ado, I'd like to kick off part one of the agenda, where we'll go into EPA's electronic reporting rule

and its electronic signature requirements. This is Preamble Part IV. A., Subpart A and B. Are there any comments on the preamble?

**Kathleen Barrowclough:** No comments on electronic reporting in that area?

**Robin Roberts:** Well, let's take this by preamble. Preamble, Part IV, section A, the general requirements section.

**Evi Huffer:** We were not planning on giving a presentation. This is basically a commentary for the public on the proposed rule. And this first section deals with electronic reporting directly to USEPA (inaudible). Electronic reporting directly to EPA, including the electronic signature certification scenario that's discussed in the preamble to the rule. I mean, if everyone is happy with it, we're happy.

**Kathleen Barrowclough:** Kathy Barrowclough, DuPont, I'm representing the SQA here. And I believe that if you're talking about the area where you're discussing electronic reporting that we have a question related to that. And it's around the basis that EPA may have had for choosing a complex submit a registration and electronic signature certification process over a system similar to that used by OPP for FIFRA'S GLP submissions whereby the submission is provided on a CD along with a signed hard copy of a document called a certification in lieu of electronic signature with respect to

data integrity.

We would like to know the rationale for the increased complexity in CROMERRR considering that FIFRA has significant legal penalties anyway for providing false information to the agency. Additionally, the FDA procedure for certification of electronic signatures is a much less burdensome process whereby companies submit a letter to FDA signifying that they're holding their people accountable for their electronic signatures.

**David Schwarz:** Let me see if I can answer at least some of the question. Probably in answer to the CD and signature page, there's nothing in the rule that prohibits that. I forget exactly where in the rule that we say it, but we say it quite clearly in the preamble that the rule does not apply to submission on CD. So in the case of the reporting that you're referring to, the final rule would not in any way interfere with that process. What the rule does attempt to address is signature and certification where there is no paper at all. And in fact, where the submission comes in, not on a physical object that you handle, but comes in in some way over the wires. And that's really the focus of the rule.

So that, I think that may explain the difference in procedure. Where things do come in on some kind of magnetic media, whether it's a CD or a diskette or tape or whatever, the

rule is simply silent on that. And that was my intention.

Does that address your question? Okay.

**Pat Woods:** I'm Pat Woods with Georgia Pacific. And I'm also here representing CEEI, the Council for Executive and Environmental Information. I don't have any written comments at this point on the recording portion of it, other than I feel I can't sit silently, which might imply that we're supportive of it. We have spent so much time trying to understand the record-keeping portion of it, and have such concerns there, that we have really not yet fully worked our way through understanding what you're asking for with reporting.

I want it to be known that we're certainly supportive of the concept of this, and have been supportive of it for some time. But what seems to be there seems to be unnecessarily complex. And I say, we have not really begun to focus on (inaudible) on the second portion. So I expect we will have more comments, but I wanted to at least go on record and say it looks as though there's more there than needs to be there.

**Howard Kruger:** Good morning. I'm Howard Kruger from Proctor and Gamble, Cincinnati, Ohio. Regrettably, I have prepared comments, but I prepared them in the context of the holistic rule in and of itself. And it's not conveniently broken down. What I had assumed, having looked at your agenda in advance, I thought you would probably just be making a couple of key

points under each one, but you would not ask people to break down their points item by item. But I actually went through here and just grabbed a couple of things, so I can make a few comments to you.

First of all, it actually states in the rule "that the rule would allow electronic reporting by regulated entities." I'm on the first page of my document. "Would allow electronic reporting by regulated entities to the EPA" and would further "allow these regulated entities to keep mandated records electronically."

Well, this actually creates a false impression. If you really didn't know better, you would conclude that there is no electronic reporting going on in the United States of America right now, and yet this is pervasively embedded into the structure of our normal business operations throughout the country right now. I think we all understand. So if you really didn't know any better, you'd say that, you know, this is not now a common occurrence. Which of course it is. And so herein lies some significant problems. How do you reconcile the ongoing status of existing technology and existing systems and the current electronic reporting with the new requirements in the rule?

And I guess really then, first and foremost, the rule really is not voluntary. And although the proposal itself

gives you the impression that it's voluntary, its requirements would be mandatory for all use of computers to meet any EPA or record-keeping requirements. And as I said before, computers are pervasively embedded into the U.S. economy with the full range of business communications, reporting and record-keeping. And this just isn't going to change; certainly it isn't going to change any time soon. So as a practical matter, for all reporting entities, you would have to comply with the CROMERRR rules. I mean, there's no way that we can go back to the days where we tried to manage our businesses with paper. It's just economically no longer feasible. So that means that somehow you'd have to adapt your existing computer systems and your reporting schemes ... to me, CROMERRR rules, or you would somehow have to go out of business. I have no answer.

I would also point out that on page 46164, column one at the bottom, the statement is provided that "many facilities do not submit documents directly to EPA but rather to states, tribes or local governments." Well we're all aware of that. And that these groups "authorized to delegate to administer a federal environmental program on EPA's behalf in lieu of the federal regulatory program."

Now, nowhere does the proposal recognize that in many instances, under such states, environmental programs where you've delegated to the states to help you out, that electronic

reporting is actually required. It's not an option. Some of the states actually require it.

In one instance, it's been reported, and I'm still trying to track all of the details on this down ... I'll have them down by the 28th of November, but in one case it's been reported, under Section 311 and 312, that if you do not report electronically, that you will actually incur a fine. Also, electronic reporting is encouraged if not, in some cases, mandated under Title V. So you have these two juxtapositions, voluntary and yet some of the exact ways in which you would have to report, there's actually mandatory electronic reporting. So to me this invalidates the concept of voluntary.

Those are the only things I could pull out of my comments right now.

**Joe Retzer:** Could I ask you a question?

**Howard Kruger:** Sure.

**Joe Retzer:** The electronic reporting that you refer to, is this reporting over a network, or is this reporting by submitting a CD or a diskette. The distinction's important.

**Howard Kruger:** I honestly can't tell you.

**Joe Retzer:** Okay, because ...

**Howard Kruger:** It's just been so short a period of time. I've tried to contact all my plants and so forth. I started out, in my thing here, to give you an idea of how complex this is, we

have 37 manufacturing plants in 24 states. And they're all subject to EPA environmental reporting requirements. And they vary all over the place. And the states do not ... it's not like there's a uniform program, every state administers the same ... it's just all over the map. So we've got 24, really, 24 different ways, and many of the states will allow, but some actually require electronic reporting. And if you don't report electronically, you get fined.

**David Schwarz:** We are certainly aware that there are many states that have EPA programs that have been taking submissions on diskette or CD. And again, let me stress that the proposed rule does not apply to those cases. It does not apply to the submission on some kind of mag medium. So I guess we would be interested in hearing about the cases you're aware of where there is actual submission over some kind of telecommunications network. Because that's really what the rule was designed for.

**Howard Kruger:** I understand now.

**Kathy Barrowclough:** Kathy Barrowclough from DuPont. And this time I'm representing DuPont on this question, because it's a follow-up to what Mr. Kruger was just talking about. The GPA, deriving its jurisdiction from Congress, mandates that EPA provide an option for reporting electronically. Since the intricacies of monitoring the environment to comply with Title V requirements are such that this monitoring cannot

logistically be done manually, electronic record-keeping and reporting in some cases is not voluntary.

Officially some states, such as Louisiana, there was a new proposal coming out in Louisiana, where they're promulgating laws requiring electronic reporting, such as Mr. Kruger was speaking of. Other states such as New Jersey have been accepting electronic reporting for some time now. Add to that the nearly universal electronic monitoring and record-keeping practices existing in the regulated environmental community, and the voluntary aspect of this proposed rule exists only in theory. And that's the way we feel about this. That it's not really going to be voluntary for us because we're already reporting electronically in many cases, and in most cases keeping records electronically.

Once it's established that the proposed rule is really not voluntary, then the cost for purchasing and upgrading systems to meet the criteria established in CROMERRR become a non-voluntary financial burden to regulated entities. Therefore, the proposed rule should be evaluated as a requirement rather than a voluntary program.

What plans does the agency have for reevaluating the scope and burden of what appears to the industry to be a non-voluntary kind of rule?

**Evi Huffer:** Just one comment, Kathy, in respect to the states.

We do understand that this could be a potential problem for companies if you have 50 states doing one thing and the federal government doing another.

We have over the years worked extensively with the states, first through a work group called SEES and now through ECOS, which is the Environmental Council of States, and also the National Governors Association. One of the reasons behind this rule, one of the purposes behind this rule, was to put together some uniform framework that could be used, not just by EPA, but also the states as we move forward with electronic reporting and record-keeping for environmental regulation.

We are doing some additional analysis now in light of the comments we've received to date. We're going back and we will reevaluate the costs. We're particularly interested in the issue that's been brought up by the industry about the voluntary nature of the rule. We were unaware of extensive electronic reporting going on in the environmental community. And again, what we're talking about are submissions over a telecommunications network. We're not talking about mag media such as CDs or diskettes. But if in fact there is extensive electronic reporting going on at the state level, then we'll need to go back and reevaluate.

**Lauren Freeman:** I have a question and then, I guess, a follow-up comment.

**Evi Huffer:** Could you please state your name?

**Lauren Freeman:** Yes, my name is Lauren Freeman, I'm with Hunton & Williams and I'm here representing utility regulatory groups. And this is on the issue of the voluntariness, and examples of existing electronic submission requirements. The utility industry is subject to fairly sophisticated electronic submission requirements under 40C of (inaudible) part 75, the acid rain program. And that is now being extended under all market-based trading programs, budget program (inaudible). Those, that is a mandatory submission requirement for utilities and it's done using actual EPA software.

It's my understanding that this proposed rule, that Subpart or Part 3 would not apply to programs like that unless the rules, in this case Part 75, were actually revised to require compliance with Part 3. So if that is not the case, then I think that needs to be made clear. For example, you have revised Part 70 to explicitly reference Part 3. But other existing programs that have electronic submission requirements, that do not currently reference Part 3, it's my understanding that this will now apply.

**Michael LeDesma:** Well, when we were drafting it, we intended to go through and identify all of the programs that we, basically all of the state programs where we wanted to look for purpose and clarity, and for purposes of making it explicit, we

wanted to make references to Part 3. We may have forgotten some programs. We have a great many programs out there ... in a short period of time, did our best in terms of identifying the programs that we thought would be ... we wanted to have subject to the rule.

If it is generally true, however, that our intent in structuring the rule was that if there is an ongoing electronic reporting program in the agency, that there is a provision that it can be carved out of the scope of the rule. So that we're not kind of stepping on ourselves in terms of the electronic reporting methods that we plan to employ here. So it may be that this particular provision that you're concerned with, that the particular program that you're concerned about, was inadvertently left out of the rule. But if that's not the case, and it strikes me that it's probably likely that we didn't inadvertently leave it out, then it's certainly something ... I think it's certainly something that we would want to leave out, that we would want to carve it out. So I think that in the preamble we've asked for comments about provisions where it's currently unclear whether or not a program is going to be subject to the rule, especially if there's already ongoing electronic reporting, to make that clear to us, so that we make sure that it gets in there, that it does get carved out. And we'll talk to the program, the

folks that run that, administer that program within the agency to make sure they do intend it to be carved out. Have I made myself clear?

**Lauren Freeman:** I guess my question then goes to, what is the default? It's my understanding in the reading of the rule that unless Subpart 3 is specifically adopted in a rule, it would not apply. The default would be it would not apply unless they were specifically adopted in a rule. Assuming we're talking about electronic submission that is required under a rule, as opposed to somebody adopting voluntarily.

**Michael LeDesma:** Are you talking about adoption of a rule in the future?

**Lauren Freeman:** No, I'm talking about existing rules, existing rules, existing final rules. Unless this proposal, or a future proposal, actually revises that rule to incorporate Part 3, Part 3 would not be required. That is my understanding. And if that's not clear, if that's not the case, then I think your proposal is unclear.

**Michael LeDesma:** Well it may be ...

**Lauren Freeman:** I think the default should be that it does not apply unless the agency or a state or somebody specifically adopts it. I will submit written comments on this, but I think some of the concern here in the room may be based on a concern that Part 3 is going to apply to their program without any

consideration of whether it's appropriate. That is, for the case of required electronic submission, where you are currently required to submit that way.

**Michael LeDesma:** When you say program, are you talking about a state program? Are you talking about ...

**Lauren Freeman:** Well the example I gave was ...

**Michael LeDesma:**... just a general ...?

**Lauren Freeman:** The example I gave was a federal program. I think there are also state programs that do require electronic submission. Pennsylvania, for example, requires electronic submission, I believe, of real-time data, emissions data. And it would be my understanding that unless Pennsylvania said you had to use Part 3, you had to comply with that, you would not have to. So that ...

**Michael LeDesma:** Yeah, I think the intent anyway ... and if it's not clear, we'll need to make it clear, is that this rule would apply across the agency. We wouldn't want to go through and revise, line by line, every single reference to electronic reporting or submission across several volumes of 40 CFR. So it makes what is a fairly sweeping interpretation of our regulations, so that this would apply generally except where there's an exclusion.

**Lauren Freeman:** I guess that's why I'm saying that's the case if you are voluntarily adopting to use this submission program.

If you're not currently required to make an electronic submission, and you're opting into doing it voluntarily, the regulation may or may not have to be revised. But if you are under an obligation, under a rule to submit electronically because a program office or a state has decided they want you to submit electronically, that is not voluntary. That is required. And it is my understanding that in order to apply Part 3 to that required submission, it would have to be adopted specifically.

**Kathleen Barrowclough:** This is an existing electronic reporting program. (inaudible)

**Male Participant/EPA:** I think we'll need to sort that one out, but you know, we'll take your comment.

**Male Participant/EPA:** To be clear, though, I think the intent is that where we have an existing electronic reporting system within the agency, that we want those folks, to the extent they don't want to kind of shift over from their criteria, we want those folks in the agency to tell us whether or not they want to be included within the scope of CROMERRR. Whether or not they want these criteria to be the ones that govern their program.

The difficulty of course is it's a very large agency; there's a great many programs and there are programs that are ahead of the curve in terms of electronic reporting. And if

they've already gone forward, again, we don't want to be stepping over their program, so we've written provisions in here so that they can carve themselves out. And if they haven't done that, and you're aware that they haven't done that, and think that they probably would want to, certainly it would be good to raise that point in comments so that we can go back to those folks and say, hey, don't you mean for yourselves to be carved out of this rule?

**Kathleen Barrowclough:** As a follow-up to that question, Kathy Barrowclough, DuPont, one of the concerns we have around that particular aspect is the statement in the preamble that until some future date, when the EPA makes an announcement in the Federal Register ... I assume it was the Federal Register ... that they are now accepting electronic reports, it sort of excludes you from sending electronic reports whereby they might already be doing that. And I think that industry's concerned you're putting a halt to the things that they're already doing because now they're going to no longer be able to report electronically. That applies to record-keeping, too, that we'll get into later, but until you publish in the Federal Register that you are now accepting electronic reporting, the industry is reading that as though, if we are already reporting electronically, we can no longer do it until we see this in the Federal Register. So I think it's a little bit of a

miscommunication, the same way as the previous speaker.

**Michael LeDesma:** I think we need to make that clear. The intent is not to stop ongoing electronic reporting. That is part of existing agency programs. We intended to have those programs carved out of the scope of the rule, unless that program office decided for some reason that they wanted to shift over to the CROMERRR approach. So to the extent that hasn't happened, and you're aware of it, you can raise that in your written comments and your comments here so that you can make sure that you have that addressed.

**Howard Kruger:** Hi, this will be my last time on this one. I'm Howard Kruger from Proctor and Gamble. I tried to get at the same point that Ms. Barrowclough made, although she did it much more eloquently and clearly than I did. I tried to get at it when I read you from the preamble where you say you will allow it. And then I made the statement that this is confusing because there's a massive electronic reporting that's going on. So I just wanted to second her comment, and the clarity that she brought to the issue.

I have two other things that I would like to bring to your attention. This gentleman here alerted me that there are some things that were not applicable, reporting on CDs and mags. The thing that I want to make sure that you understand is there are, and I will use advisedly hundreds of thousands, and this

is a catch 22, hundreds of thousands of companies ... let's say reporting entities that are keeping records electronically on existing equipment, that would be used to verify that you had not met a threshold for reporting, irrespective of whether you're reporting telecommunications, on magnetic tape or on CD. So there are ... this is the catch 22 where regardless of exclusions you make, you're going to have to somehow come to grips with this reach over to record-keeping that people are now using in current systems.

And then the other question, I would just like to hear you talk a little bit about, is how is EPA going to, with all the huge numbers of systems that you have, are you going to come into compliance with this rule, from a standpoint of these requirements?

**Joe Retzer:** I'm not sure I quite understand that last question, but I think if you look at the Central Data Exchange, the idea is that EPA, at moving towards having all direct reporting coming to EPA, come through one place, one web portal. And that portal will be designed to meet the reporting requirements that are in this rule. And that's why, for example, on things like the acid rain program, for awhile that program may continue its reporting as it is. But it may eventually shift over to Central Data Exchange, as other programs are doing, as well.

**Howard Kruger:** Even though you have CDX, you're going to still have states to whom you delegate and move us?

**Joe Retzer:** That's correct.

**Howard Kruger:** Okay, well how will ... I mean, I consider that part of your responsibility.

**Joe Retzer:** Right.

**Howard Kruger:** How will you comply with the rule? How will your delegated entities ... if I go out and hire a contractor for an ...

**Joe Retzer:** Are you asking how will the states comply with this?

**Howard Kruger:** No, I'm asking how will you? How will the ... you're delegating the states. I hold you accountable. Not the states, you. The EPA of the United States of America.

**Joe Retzer:** So the question for us is how do we hold the states accountable?

**Howard Kruger:** Yes. When they don't have the CDX and all these other kinds of fancy things.

**Joe Retzer:** Well, we will ...

**Howard Kruger:** I'm saying this to you ...

**Joe Retzer:** We will be addressing, we'll be talking about that, I think, later this afternoon. But we do have the criteria applied to states and EPA needs to approve the state systems.

**Howard Kruger:** Okay, well we always need to remember that in order for a compliance system to be in existence that someone has to budget the money, collect the money, dedicate the money, spend the money, actually spend it on equipment that will allow for a compliance. These are real; you can't just do it theoretically. It has to be real life, real time.

**David Schwarz:** Yeah, one of the things I guess to kind of keep in mind in our thinking about this rule is that EPA is designing and is building and actually has started receiving reports through something called the Central Data Exchange. The idea here is that direct reports to EPA, as well as batches of files from states, are going to be coming through one portal at EPA. And since we'll be having one face, the idea is that we need a sort of standard set of approaches or standard set of requirements that should make it easier on companies not having to deal with ten or twelve or fifteen different programs for direct reporting.

And we've already started a couple of programs now, one with direct reporting from laboratories under the unregulated contaminants rule, in the drinking water program. We've also had some talks with release inventory reports, come directly to EPA through Central Data Exchange. Now we're working on a couple of areas under COSCO (phonetic) like health and safety studies, as well.

So the idea is, we're going to have a sort of standard approach to electronic reporting and registration for companies doing direct reporting to EPA. We've got this underway now; we've been working with an interim facility at this time. And we're going to have our procurement underway to have a full-fledged, fully operational Central Data Exchange up and running late next year.

And part of the idea of this sort of announcing that we're ready, that EPA is turning on electronic reporting program by program, is based on the idea that we have to get ready, have to do the work, have to have the hardware and software in place for each program to be able to say, okay, we're ready to receive electronic reporting. The idea there wasn't to prevent or stymie electronic reporting that's going on now. The idea was simply to say, you know, we're not going to be ready to receive electronic reporting all at once.

We're going to be turning on programs one after the other when we're ready to receive them. But we don't want people willy-nilly sending us email saying here's my electronic report until we're really ready to receive them.

**Evi Huffer:** Are there any questions or comments on the Central Data Exchange?

**Bill Barta:** Bill Barta from FMC Corporation. I have two questions. There's a revision in the rule about upgrades in

the CDX system, major and minor. And I have two comments on that. First of all, I think you need to define a little more definitely what that exactly means to the user group. And secondly was, we felt within our IT group in FMC that the lead time for the major was probably insufficient. We thought maybe another six months or a year because of the budgeting process within the corporation. We'd need some extra lead time. I think that was a 12-month target to *meet the format*.

And the reason we mention that is that typically something is done in June, for example, we have budget process ... October, November an actual (inaudible) probably would take longer than that because of our cycle within the company. I think many other companies would be in that same situation. So I think maybe you might want to consider that time frame to discuss with the clients.

The second feature that was brought to my attention was how long are you going to keep records electronically on CDX? There are programs that might have a pretty long retention time and I imagine that you might want ... at some point in time, when something is out there five to seven years, you're probably going to have to migrate to another system, and if you did that, how would you coordinate that with the submitter who probably would be in the same situation. And if the agency used a different migration path than the submitter, we

potentially could have a disparate record that potentially could not match, depending on what kind of software, hardware.

**David Schwarz:** Can I ask you a question? Are you referring specifically to what we call a copy of record?

**Bill Barta:** Yes. Well, could you explain more about the copy of record because I had some uncertainty about what that means.

**David Schwarz:** Well that is the submission with the electronic signature, signed over again by the agent ... well, by what in effect would be an agency electronic signature. And that would sort of serve as the surrogate for the paper, originally, which of course we won't have because there won't be any paper. And in the rule, we've talked about making that available to the submitter. And it sounds like what you're saying is that if we migrate the way we keep our copy of record, we might want to make the migrated version available to the submitter.

**Bill Barta:** Okay, okay.

**David Schwarz:** That's a good point. I hadn't even thought about that.

**Evi Huffer:** Were you through with your comments?

**Bill Barta:** Oh, sure.

**George Britton:** George Britton with the Aventis Crop Science. It is very likely in migration scenarios that migrating upward may not generate exactly the same information that you had previously. And if you are like software updates, people don't

always upgrade Windows at the same rate as everybody else ... there are things and features in the new version that will not be available backwards. So if you're submitting backwards, there's a problem there with having information come back to whoever submitted it, if you're on different operating systems, for example. That's where the migration issues ...

**David Schwarz:** Right, right.

**George Britton:** ... and technology has changed so dramatically in the last five years. When was the last time you read a five-and-a-quarter floppy or eight-inch floppy?

**David Schwarz:** Right, right.

**George Brittin:** Those kinds of issues in migration.

**David Schwarz:** Yes. We would welcome any suggestions that people have in terms of how best to handle these kinds of issues.

**Mary Catherine Fish:** My name is Mary Catherine Fish, and I'm with MCF Consulting, Inc. and I had a question that went back to some of the earlier discussion about the lists of subjects and the parts that are affected. You mentioned that, in terms of reports that are already beginning to come through CDX, TRI and TSCA. I had noticed that those are two parts that are not listed in the list of subjects in the regulatory language. There's not a listing of Part 370 or Part 700.

So I'm confused about what it means, what is the

difference between those that are specifically listed and Part 70, etcetera, and those that are not. And I think to reiterate the previous question, if they're not listed, is the default that they are affected? Or that Part 3 is applicable? And why were some listed and have proposed regulatory language and others, like Part 700 or Part 370, not included in the list of subjects for the proposed rule? It's confusing as to what the reporting requirements will apply to.

Evi Huffer: Right, and I think I can see a need for clarification here. And this follows up on your comment earlier. What you see listed in the Federal Register, it says 40 CFR Parts 3, 51, 60, 63 ... those program sites refer to specific provisions for the state privacy regulations and they're not ...

**Evi Huffer:** ... clarify (inaudible)

**Male Participant:** (inaudible)

**Evi Huffer:** In the Federal Register notice, at the top of the notice, it says "What parts are affected by the proposed rule?" 46162. I assume when people are stepping to the mike a referencing sections that aren't being referred to in the rule, they're referring to this, to parts that are specifically sited. Again, these parts are specifically sited because they're regulatory language is being changed under their state program positions.

**Michael LeDesma:** I think again that the answer is that unless a state ... unless one of our programs has explicitly opted itself out of CROMERRR, the default is that a program would be affected by CROMERRR, would be covered by CROMERRR.

**Kathleen Barrowclough:** Kathy Barrowclough, DuPont. And this is a follow-up, when you were talking about the copy of record and it being maintained by EPA. It seems to me that I at least interpreted what I was reading to mean that this copy of record would be sent back and that we, as the industry, who had submitted it originally would be required to keep the one that we sent as well as the copy of record that was returned from EPA so that we would be archiving all of that. It didn't sound that way based on what you said a few minutes ago. Could you sort of clarify that?

**David Schwarz:** I'll try. There is no requirement in CROMERRR that the submitter maintain what we're calling the copy of record. We're not adding any new record-keeping requirements in that area, so what we say is that we will make this available to you. You can take it or not, as you choose.

**Kathleen Barrowclough:** And again, on one of the other areas that we've just talked about, where the certification and the electronic signature certification aspect in particular. One of the concerns that I have heard raised is how quickly people will be able to receive that certification. For example, there

are changes in personnel that occur and we don't want to impede our ability to report electronically because of those sorts of things. So we would like to make certain that it's going to be a very quick turnaround on the certification scenario.

And two, in I believe the ICR that was submitted on the cost benefit analysis, it appeared that there were very few, maybe like two people per facility that might be needing to get this certification. And it is our, within DuPont, we have many more people than that who submit electronically and would need to be registering. So that number is greatly, very much larger than what we read in the ICR. So those are two points, if you would.

**David Schwarz:** Well, the second point, I mean, we'll obviously ... any information that you could give us on that would be of interest and we'll take it into account.

I guess with regard to the first, by the certification, I assume you're talking about the registration with CDX and the assignment provision of a signature mechanism. Right? Our hope is that that can be fairly quick. It can be done pretty much online. I guess in our current prototype, the turnaround is less than a week. I'm kind of looking at a colleague in the back. Kim, is that right?

**Kim Nelson:** (inaudible)

**David Schwarz:** Three or four days, something like that. So

hopefully that would be timely.

**Lauren Freeman:** Again Lauren Freeman with Hunton and Williams. And I have a follow-up question to this applicability to existing programs and existing electronic submission requirements, for example Part 75, you explained you thought that this program would apply when finalized to that, unless other subparts were carved out. What procedure do you envision that carve-out to be accomplished through? And did you account in your ICR and other burden estimation requirements, did you take into account the burdens associated with requiring other programs to convert to this subpart?

**David Schwarz:** The ICR addresses burden on the public. It doesn't address ...

**Lauren Freeman:** The burden of the regulated entity ...

**David Schwarz:** I see.

**Lauren Freeman:** ... that is making a submission under an existing program. If this applies, unless that is then separately carved out, what mechanism would you carve it out in, and did you consider the impact of hundreds of electrical utilities, for example, having to come up with systems that meet Part 3?

**David Schwarz:** I guess the answer to the burden question is that we did not consider that, and probably ought to. But I guess in terms of carving out, again, to echo what Michael

LeDesma said, hopefully in your comment, you will be able to alert us to areas that we missed. We may need to go back to our programs and ask them if they wish to be covered or not, and probably in a number of cases, at least in the short term, programs would wish to continue under their existing system. And we can reflect that in final rule. There is a place for a list of exempted programs or excluded programs. So that would be the mechanism there.

**Joe Retzer:** I also think if we were to bring in a program like the acid rain program that the only really change for the company ... you wouldn't be changing the software or the file structure or anything of that sort. The only change would be how the registration would work. I don't know exactly how that program works now, whether you dial up, whether it's an FIFRA (??) or whatever, but under CDX you come through a website (inaudible) web-based (inaudible) system or not. But the idea, for example, what we've done in working with TRI, our TRI reporters, is that we haven't changed the TRI software at all. What we did is just simply provide people an option to go to a website and send electronically instead of either printing it out or mailing a diskette. And what we're doing with the new to try the TRI version that's coming out next year, is being built into the CDX just like on Turbo Tax you can say, yeah, I want to send this electronically and follow a couple of

instructions and send it electronically. That's what will happen with TRI.

So what we're trying to do is we're putting in, particularly, you know we haven't worked with ... the reason we haven't done acid rain yet is that it's already going electronic and we're more concerned with bringing in the programs that are not electronic now to provide that opportunity. But at some point, if we decide to work with the acid rain program, and they say, yeah, great, and come through Central Data Exchange, basically the idea would be to make it as seamless as possible. The only thing that would probably change would be how the registration would work.

**Lauren Freeman:** Again, Lauren Freeman with Hunton and Williams. Let me just explain why I'm so concerned about the applicability. It's not necessarily the registration process or whether you're doing it through a website or through the existing software that EPA provides utilities. My concern is with some of the other requirements. For example, the signature verification requirements, the requirement that the report actually be physically submitted by the person who signs it, which in many cases is a vice president or somebody who is not ... and also the requirement that you re-back data. We're talking about three months of hourly data for dozens of parameters. You can't physically read that on a screen. So

I'll save my comments for later, but if those ...

**Male Participant/EPA:** So one thing that might be really helpful is if you think about your company being eventually part of the CDX structure, what are the particular requirements like that one, that you think would be a problem?

**Lauren Freeman:** Well, we're trying to decide how much we have to comment on this program by determining whether or not we'll be affected by it, and whether we'll get another chance to comment on it.

**Male Participant/EPA:** I guess eventually the agency is thinking that direct ... all the direct reporting will be done through Central Data Exchange. Simplify security, simplify registration. Should eventually simplify for companies because they'll have one place, one system on the (inaudible) to send data. Since that's the program already sending stuff electronically, it's not on the top of our list of programs to bring in. But I guess I would say yes, you should pay attention to it, because probably eventually you're going to connect with CDX. So it would be worthwhile to make comments on the reporting aspects, such as viewing the data before you send it in.

**Lauren Freeman:** All right. Thank you.

**Kathleen Barrowclough:** Kathy Barrowclough, DuPont. And following up what Lauren just mentioned about the person who is

submitting not always being the person ... we delegate authority within DuPont. So that while it might be a vice president's name, it might be delegated for someone else to actually be doing that submission. So it makes us believe that there's going to be a more complex process that's going to be associated with that registration ... submitter registration process. Do we have to register all of the people who need, who touch that document, or do we need to just, the person who we have delegated as the person who submits?

**David Schwarz:** I think our intention is that the person who submits, signs and certifies is the person who gets registered, gets the electronic signature device. If there's something wrong with that idea, then we need to know about it.

**Kathleen Barrowclough:** Again, you answered my question. Again, one of the concerns that I might have, having come here today and hearing some of the clarifications you're giving, and some of the comments you would like to see around certain things, such as when we say we see this part, this part and this part mentioned, what does that mean for the others ... is that the people who are not aware of that will probably submit comments just saying please clarify this. And once you've clarified that, then they may have those other comments that you're asking for us to do, to give to you. So I guess I'm concerned that the entire regulated community won't be aware of some of

the comments that they need to submit, based on what we just have heard from you.

**David Schwarz:** I guess to the extent that it seems that that's a widespread ... that the confusion is widespread, we'll need to consider how to rectify that.

**Michael LeDesma:** We certainly don't want to, we don't want people not to be commenting, or commenting completely that they misunderstand the language. On the other hand, we don't want to get into this endless do-loop, where we get questions, comments, that we need to clarify. That would not be productive.

**Howard Kruger:** Hi, Howard Kruger from Proctor and Gamble. I would just like to second ... sometimes what we're doing here is we're saying "yes, yes, yes." I would like to second the comment that was just made by Ms. Fair about once you clarify some things that are not understood, and a lot is not understood about the CDX. When you start to read through the proposal, several things jump out like, yes, there's going to be signatures, electronic signatures. Yes, there's electronic reporting. Yes, there's electronic record-keeping. But then there's this mysterious page after page about CDX, and I would just volunteer ... or I'll say, from my standpoint, that's the least understood part of the proposal. And so when you do make clarifications, then maybe I can be a little smarter to begin

to make some comments to be helpful. But right now, I would say that's sort of a black box, and that if you don't get a lot of comments, I think you should not assume that everything's hunky-dory, but that people are really confused by this and they don't understand it.

**(BREAK)**

Kathleen Barrowclough: Kathy Barrowclough, DuPont. One of the questions that we've come up with is about, will the Department of Energy and the Department of Defense, their massive remediation sites and that sort of thing ... will they have to follow this requirement for either reporting or record-keeping?

**David Schwarz:** I was going to defer to my colleague as general counsel, but my understanding is that, to the extent that they are a regulated entity, they would have to comply. Yes.

George Britton: George Britton of Aventis Crop Science. In terms of the CDX, I represent the (inaudible) side of it for Venice Crop Science. And I am concerned that our pesticide registrations are generally significantly larger than a few pages of numbers. And how is the CDX planning to address electronic submissions of the pesticide registration process?

**Joe Retzer:** We may not. That is, to the extent that people are sending basically CDs and not electronic files over a network. And Central Data Exchange and CROMERRR don't apply. And if, you know, continuing discussions with that program, if

that seems to be the most efficient way to continue doing that business, then ...

**George Britton:** Are you saying that CROMERRR does not apply?

**Joe Retzer:** CROMERRR doesn't, as we mentioned, CROMERRR does not apply to data submitted on magnetic media, that is data that doesn't come over a network. Data submitted on a CD or data submitted on a diskette, or something of that sort, or a tape if you had ... CROMERRR does not apply.

**Evi Huffer:** Let me add to that. One thing to bear in mind is that this is an omnibus rule. CROMERRR, in itself, when promulgated, does not turn on electronic reporting for any program in particular. One of the requirements for electronic reporting that's stipulated under Subpart A, is that the agency has to announce that it's ready to accept electronic reports under a particular program.

**George Britton:** Over a network.

**Evi Huffer:** Yes, over a network. So the issue of having to exempt specific programs may be moot. Basically it may be that, for programs such as the acid rain program that already has an electronic reporting program in place, the program will just continue with that and you'll never see an announcement that says you will now use CDX. I mean, the way the rule is structured, there is a turn-on feature.

**George Britton:** This may be the follow-up to that. But isn't

the rule, it talks about things being modified, maintained, distributed or reported electronically ... like all the businesses are in fact doing various phases of that electronically already. And doesn't that make the reporting on media mute, and make it mandatory at that point?

Male Participant/EPA: It may ... this is actually something that we'll talk about under the electronic record-keeping part of the meeting. But it may bring them within the scope of the electronic record-keeping portion of CROMERRR. But it would not necessarily bring it under the scope of the electronic reporting part of CROMERRR.

**Evi Huffer:** Something that has been brought to our attention, and that we will probably have to deal with in the final rule ... it was not intended to include records or reports under the definition 'electronic' just because they were created on a PC. For instance, the FDA rule has a typewriter exemption. When the PC is used as a typewriter to create documents, it's not intended to necessarily fall within the scope of the electronic record.

**George Britton:** There's some issues in that vein about when does a record become subject to that rule? It's still up in the air four years after it's propagated.

**Bob Bessette:** I'm Bob Bessette with the Council of Industrial Boiler Owners. We represent energy and environmental issues

for most of the boiler owners in the country. Are you guys going to use the FDA interpretation of electronic record-keeping and reporting requirements. Or if you're not going to do that, how are you not going to do it? It puts an onerous burden; there's not one ... I don't think there's one industrial boiler in the country that goes back and uses paper anymore to collect data. And these are small businesses. These go from little bitty boilers, all the way up. And they're all sources that are regulated. If they're forced into adding your implementation requirements, there is no cost benefit.

Right now they're using the electronic medium, laptops, they're using small PCs to handle a lot of the data. If they have to go to major record tagging stuff, it's going to raise the cost so much that they're probably going to want to go back to paper. But if they're using electronic now, they're doing ... because it's less expensive than using paper. So it's going to add a significant burden to 22,000 potential boilers. If you're not going to use the FDA's interpretation, and we can keep the record-keeping and reporting just the way it is today, then the overall attentiveness is very very good. But if it's going to go to that next step, it's a killer.

**Mark Duvall:** My name is Mark Duvall. I'm with the Dow Chemical Company. I had several points that I wanted to make

about the record-keeping proposal, record-keeping aspects of CROMERRR. The first and the most important one of which is that record-keeping is presented in the preamble as voluntary, but our analysis is that it would be mandatory in practical effect. The reason for this is that the definition of an electronic record is very encompassing. It captures any data that runs through a computer at any point in its lifetime. If it is created on a computer, if it is maintained on a computer, if it is manipulated on a computer, if it is stored on a computer, then it's an electronic record. And anything, anytime a computer is involved with data, it's an electronic record.

Once it becomes an electronic record, then it is subject to the rule if that data is used in connection with electronic record-keeping, in connection with record-keeping for EPA purposes. And today, every facility in the United States that is regulated, has record-keeping responsibilities under EPA requirements, keeps those records electronically using a computer. As a result, there is no choice about choosing to keep records electronically. There is only the fact that everyone does and everyone must keep records electronically. So the fact that this is not a voluntary provision at all is very significant. It's the most significant misperception about this rule, this proposal.

There are a number of consequences that come from the fact that it is not voluntary, one of which is public notice. Under the Administrative Procedure Act, there is a requirement that EPA give public notice of what it proposes to do. The public notice on CROMERRR announced that the record-keeping provisions were voluntary. If you've read through the notice, it said that about 428 facilities per year would choose to subject themselves to the record-keeping provisions. And yet approximately 1.2 million facilities in the United States would be subject on a mandatory basis to CROMERRR's record-keeping provisions. There's a world of difference. The public notice that was provided to the public by EPA is terribly deficient. And I think EPA should be concerned about the prospects of a procedural objection on judicial review that the public has not had an adequate opportunity to comment because of the way the record-keeping provisions have been presented.

Third, my next point is that because EPA considered the record-keeping provisions to be voluntary, it chose not to conduct a regulatory flexibility analysis to discuss the impact of CROMERRR on small businesses. In fact, the preamble says that this would have a net benefit for small businesses. And yet, small businesses would be affected by the record-keeping provisions just as big ones would be. And they would have to go out and they would have to buy expensive retro-fitting fixes

for their computer systems. Or they would have to go out and buy new computer systems that would meet the CROMERRR requirements. A huge impact on small businesses which is not addressed by EPA because it did not conduct regulatory flexibility analysis. So I would strongly encourage EPA to go do one.

Next, EPA has not justified the costs of CROMERRR, given that it is, in fact, a mandatory program. The regulatory, I'm sorry, the cost benefit analysis conducted for EPA and discussed in the preamble indicates the costs of the record-keeping provisions exceed the benefits. Now, having a regulatory proposal where the costs exceed the benefits might make sense if it were a voluntary program. But it's not. And accordingly, EPA has not justified the costs of the record-keeping program.

Just as we heard some concerns already about how currently there is ongoing reporting, electronic reporting, obviously there is ongoing electronic record-keeping today. And yet, CROMERRR says that there would be no allowable electronic record-keeping until EPA published a notice in the Federal Register that it was prepared to accept electronic record-keeping. What that means is that the 36 EPA regulations which today currently allow explicitly electronic record-keeping, and the many more EPA record-keeping provisions which implicitly

allow electronic record-keeping by being media-neutral, would be suspended and instead would have to wait. People could not use computers until EPA published a notice saying that they could begin to do so. The reason for the notice that EPA's prepared to allow electronic record-keeping is entirely unclear, since EPA itself does not have to do any preparation for electronic record-keeping by the regulated entities.

Next, CROMERRR's record-keeping provisions would be inconsistent with the Government Paperwork Elimination Act because they would treat electronic records less favorably than paper records, contrary to the purposes of the statute, and would actually discourage electronic record-keeping. EPA adopted CROMERRR, or proposed CROMERRR, in large part because of the Government Paperwork Elimination Act which, among other things, directs agencies to make available electronic reporting and electronic record-keeping by October 2003. Electronic reporting is not currently allowed in a number of areas, but electronic record-keeping is. Electronic record-keeping is ongoing. It is not prohibited. It is explicitly allowed in some regulations, and it is implicitly allowed in others.

And so EPA does not have to do anything under CROMERRR to fulfill the GPEA's requirement that they make electronic record-keeping be available with one exception. And that exception would be that certain record-keeping requirements

have, as stated in the regulations, words which imply paper, whether a written signature or other kinds of words which suggest that electronic record-keeping would not be permissible. All EPA has to do under CROMERRR is to say words such as that can be interpreted to allow electronic record-keeping plus EPA needs to adopt an electronic signatures rule that would allow rules to be signed electronically. Other than that, there is no need for a record-keeping provision in CROMERRR in order to effectuate the Government Paperwork Elimination Act.

On the other hand, the stated purpose in the preamble, or one of the stated purposes of the record-keeping provisions is to improve ... that's EPA's words ... the reliability, the security, the anti-fraud aspects of records that are now kept to improve the level of security above that of paper. What EPA is doing is taking an opportunity presented by the Government Paperwork Elimination Act to increase, above the gold standard of paper, the level of security for records required by EPA. And that is, in fact, treating electronic records less favorably than written, than printed records, contrary to the purposes of the GPEA.

OMB presented guidance to executive branch agencies on how to implement the GPEA. And in that guidance, OMB directed EPA and other agencies to conduct a risk analysis. A risk analysis

on the need for security provisions, in other words, what is needed to prevent fraud and what is not needed to prevent fraud? And what is the cost of provisions to deter fraud or to detect fraud?

So if both a risk analysis and a cost benefit analysis are needed to address the security aspects, according to the OMB guidance. The OMB guidance says do not do a one-size-fits-all approach because there are different risks and different costs associated with different kinds of situations. And in CROMERRR, it certainly appears to present only a one-size-fits-all approach. The least significant record-keeping requirement in all of EPA requires exactly the same anti-fraud provisions as the most abused, most risky record-keeping provision. One size fits all for the CROMERRR, contrary to what OMB has recommended.

The record-keeping rule docket has very little in it to support or even discuss record-keeping under CROMERRR by regulated entities. There is some information there on CDX, on electronic reporting, a certain amount on electronic signatures, but there is virtually nothing there on electronic record-keeping by regulated entities. The problems of electronic record-keeping under CROMERRR are significant. There are very challenging technical requirements there. Their cost, their difficulty, their solutions, their impact, are not

discussed in documents which currently appear in rule-making docket. The EPA does not substantiate the reasons for this proposal on record-keeping. Better, a court on judicial review would have to conclude that the proposal was arbitrary and capricious.

EPA has substantially underestimated both the costs and the technical challenges associated with the record-keeping provisions. It estimates them at \$40,000 plus an annual cost of \$17,000. EPA's own cost benefit analysis describes those costs as prohibitive for any system which is set up solely to comply with EPA record-keeping requirements. Since people who are required to keep records for EPA purposes already have their computer systems, any changes to implement CROMERRR requirements would be solely for purposes of meeting EPA CROMERRR requirements. And yet this \$40,000 figure, prohibitive as it is, is considerably underestimating the actual costs. For example, under the FDA rule, Part 11, pharmaceutical companies have found that their costs are in the millions of dollars to comply with part 11. They have been trying for four years to come into compliance. Many find that they have only made part of the journey and there are millions of dollars needed to continue to be spent. The costs are very large here.

Just an example is Microsoft Excel. Excel is a very

widely used software program for collecting data that is required for EPA purposes. And yet no company, no EPA-regulated facility in the country could use Excel for that purpose without buying a fix, because Excel does not have an audittrail (phonetic). There is a product that's being marketed on a website and being presented to FDA which claims to provide an audittrail to Excel. The Dow Chemical Company talked to them; they want a lot of money for this system. Every facility in the country that uses Excel would need to buy that patch or a similar one, or a comprehensive system to provide the audittrail capability which is not currently in use in almost all computer systems today. The costs of CROMERRR's record-keeping provisions are more or less on the same order of magnitude as Y2K. Huge numbers, and yet EPA has not addressed those numbers in any of its analyses to date.

In summary, there are many problems with the record-keeping provisions in CROMERRR. And EPA simply can't fix them by, for example, putting out a supplemental notice of rule-making, or hiring another contractor to do another report. These are fatal problems. EPA should sever the record-keeping provisions of CROMERRR from the rest of the proposal, allow the CDX, the electronic signatures, electronic reporting provisions, to go forward. It should withdraw the record-keeping provisions and return them for further analysis. Thank

you.

Are there any responses to what I'm saying?

**Joe Retzer:** (inaudible)

**Mark Duvall:** However you want.

**Joe Retzer:** It's just a question of, you know there are nine criteria that are listed in the program records. Are there some of those criteria that are the ... trigger the costs. I mean, you mentioned particularly the audit trail. Another way of looking at it would be to look at those individual criteria and comment on those (inaudible).

**Mark Duvall:** Well certainly the audit trail requirement is an important one because most systems today don't have audit trail capabilities. Another troublesome requirement is the requirement to maintain electronic records for the entire record retention period.

**Joe Retzer:** Can I ask you about that one? Because the requirement for maintaining records for the entire retention period isn't a CROMERRR requirement. It's a requirement of the air program (inaudible). What are companies doing anyway? So if the company has decided, or finds it most efficient to do electronic record-keeping, that they're under provision of a program rule, like an air program rule that requires (inaudible). How are you addressing that as part of CROMERRR? I don't see that CROMERRR necessarily adds cost. Isn't it

really the program rule that's ...?

**Mark Duvall:** No, the CROMERRR is actually adding the costs. The reason being that under today's rules it is acceptable to print out electronic data and keep the paper copy as the retained copy for the retention period. But CROMERRR would require the electronic copy to be migrated from generation to generation of hardware and software for the entire retention period. The Dow Chemical Company's internal record retention policies indicate that after a certain number of years, all electronic documents must be reduced to paper precisely because of this concern as data is migrated across hard software and hardware, data is lost. It's very ... and we're faced, under the CROMERRR record-keeping requirements, with the dilemma of either maintaining legacy systems solely for regulatory compliance purposes, perhaps for decades, or else migrating across different hardware and software and doing the best we can with the inevitable data losses and corruption that occur.

I might add that EPA has to some degree the same record retention problems, to the extent that under the FOYA (phonetic) or other requirements that EPA itself must keep data electronically for the retention period. EPA is surely finding itself in a dilemma of finding a cost-effective technical solution. EPA with all of its resources from the government, supported by the taxpayers, is finding that requirement

extremely challenging. And yet every small business, every large plant, every one of 1.2 million regulated facilities that keep records has exactly the same problems under the CROMERRR record-keeping provisions.

**Kathleen Barrowclough:** ... and first of all, I think I'd like to support the comments that Mr. Duvall made on behalf of Dow for DuPont, as well as for the society of quality assurance. Many of our comments are very similar in nature to Mr. Duvall's. And just to illustrate one particular instance around the cost of electronic records, DuPont, at just one of our GLP (phonetic) facilities, and this is just a GLP tox lab, we are implementing just two of our systems, upgrading electronic data collection systems in order to allow for appropriate electronic archival for next year. And this is really for Part 11 compliance, which would be similar to what we'd have to do for CROMERRR. And that's going to cost us 1.2 million dollars. This is just two systems in our tox lab in order to make them acceptable as electronic archiving tools.

Along with that, we have 71 other software applications in that same laboratory collecting raw data for GLP purposes that will have to go through some sort of similar gap and risk analysis and put into place some of the things that are necessary.

As Mr. Duvall mentioned, one of the options we have had in

the past was printing out, so our analytical instruments that we've had in the past, we have printed out hard copies and called that our raw data. That will no longer be acceptable. And while we have maintained our raw data anyway, we have kept that electronically while we still have called the printout, we will actually be required now to migrate that electronic data and there's a phenomenal cost associated with that.

And when I say that that's just our tox lab for GLP purposes, when I started working across DuPont, looking at the other programs within DuPont that will be similarly impacted by CROMERRR, it was phenomenal the response I got from our environmental areas for the manufacturing companies, the people who have to report water data, air data, all of those different things ... all of the things that monitor and gather that data are electronically computer generated type pieces of equipment. So that all of that information, all of those systems will come under CROMERRR, according to the way we read CROMERRR as far as record-keeping.

And if that's the case, the cost is going to be phenomenal because, while at our GLP facility, we already had the systems I talked about upgrading for archival purposes already had audittrails on them. They already had a lot of the things that we consider necessary for the validity of that particular data.

But now we're talking about when you manipulate that data

in some other fashion, if you manipulate it electronically with some other system, that system will also come under the rule. What we do now is we say, if you're manipulating it electronically elsewhere, for example, we collect data in a data collection system. We have to run it through a statistical program. Not all of our systems are connected. So therefore, we may collect that data in one data capture system, report it out to a file which is not protected with audittrails and that sort of thing, then put that report through our statistical program which is again protected through audittrails and the appropriate things, but recognizing that we can always go back to that original data, that original report. You can run it again, you can see that it's the same thing. If all of those systems are required to meet CROMERRR, then you're required to have those audittrails all along that whole pathway. And it really increases the cost associated with maintaining electronic records.

**George Britton:** George Britton of Aventis Crop Science. A problem with the record-keeping, and a long-term keeping of these things. Our (inaudible) company is involved, has just come through a merger. We're fixing to be bought again at the beginning of the year. As you brought these two companies together, you had two different laboratory electronic data collection systems functioning within. One group had one, the

other group had the other. And the merging process, you've got these two systems side-by-side, neither one of those two systems will talk to each other. And if I had to keep that data for 30 or 40 decades, I run into the problem if I cannot do this, even if I upgrade the software.

One particular case is the water's (inaudible) system, version two or version three. Same company, same data, it will be read forward. But that nine version three, if I am to take that information and reprocess it with the same parameters it was collected with and printed out the first time, I will not get back exactly the same information. It will be close, off a few significant decimal places, because the peak algorithms have evolved over time. Keeping a system for a few years, to be able to recreate exactly the same information is a viable thing that you might do. But keeping it, at some point and time you're going to need to print it out and go forward or some criteria has to get to be in there ... how close in the audit process does it have to be to be considered exact? Just simply because the software algorithms have evolved over time. Even though I keep it, got all the measure data there, tell you who's collected it, da da da da da. But I still can't produce precisely the same result because the software has changed. Do I have to keep systems for years just to be able to go back and do this?

Normally in the EPA's process, there's usually a reasonable period of review for the data, which is perfectly fine to keep that, but say in a reasonable period of time that you could allow printing out of that information, and let that be kept long term, and not have to keep the functionality of that electronic record within 20, 30, 40 years, (inaudible) some of our problems in the industry have been. This is where the record-keeping in the electronic format is really burdensome.

**Charles Reese:** Good morning. I'm Charles Reese with BASF Crop Science. First of all, I want to say that BASF agrees with Mr. Duvall of Dow, the costs associated with these systems. We are in the process of implementing a system that will keep our data electronically and the cost of that system; the price tag is starting to go up the scale and is approaching 4 million dollars for a metabolism chemistry residue data collection system. And these costs don't even include the costs of taking individual instrument component systems and capturing the electronic data on those, and bringing them in to the main system. There are going to be more costs associated with that.

But my question here today has to do with Subpart C, 3.13. We talked about this rule increasing costs, and it says you must produce accurate and complete copies of any electronic record or electronic document and render these copies readily

available in both human readable and electronic form for onsite inspection and offsite review for the entirety of the required period of record retention.

Our question is, what does this exactly mean, specifically referring to offsite review for an electronic record by the agency? These are very intricate systems, they have multiple components. What does the agency expect when it comes to reviewing an electronic record in an offsite review? Are we supposed to provide software and/or hardware to the agency offsite to preview these records?

**Evi Huffer:** The intention wasn't for the facility to provide the agency with software and/or equipment. There are, in our current regulations, a requirement for offsite review. You'll have to go back and take a look at that. I would assume the way it's being carried out under the current regulations is that you're giving them a hard copy and they're walking away with it. I don't know if that in fact is the case though.

**Charles Reese:** Just to capitalize on what you said there. If you're able to take a hard copy review, a hard copy printout and walk away with a record like this, it can be argued that, here, with an electronic record as stated that, these electronic records, the printouts, I mean the records themselves have meta data associated with those. The meta data include the, maybe the methods or the sequences, or even the

algorithms of the computer that generated the data in the first place. So now if you can accept a hard copy printout of review in that case, why must the meta data and all this audit trail and everything also transfer with the electronic record when it's being stored electronically if the hard copy printout is essentially what you can take away? Does that make sense?

**Evi Huffer:** Yes, it does. Before you walk away, can I ask you a question? In the cost that you cited for building your system, 4 million, was that a system to comply with the FDA rule?

**Charles Reese:** No ma'am.

**Evi Huffer:** No?

**Charles Reese:** No. We are strictly an EPA facility, EPA regulated facility under FIFRA and this is strictly to capture data. In a sense it's an electronic notebook system where the lab technicians won't be able, won't have to write down anything on paper, they will be inputting their stuff electronically, and storing the record electronically. And it's going to have audit trails and everything as part of that.

**Evi Huffer:** So it's basically the cost associated with building the system irregardless of CROMERRR?

**Charles Reese:** That could be, yes.

**Evi Huffer:** All right; thanks.

**Walter Retzsch:** Good morning. I'm Walter Retzsch. I'm

representing the American Petroleum Institute. API represents over 400 oil natural gas companies in the United States whose operations extend from exploration and production through distribution, refining and marketing. A large number of oil and gas industry facilities maintain a broad range of environmental records, many of which are used to comply with EPA reporting requirements and we are very concerned with this proposed rule.

API supports EPA's efforts to establish voluntary electronic reporting mechanisms. API member companies welcome the opportunity to submit reports to EPA electronically, as long as the systems developed are cost-effective and secure.

However, the usefulness of electronic reporting will be severely undermined if EPA proceeds with the record-keeping provisions in the proposed rule. Although we have not completed our analysis of the rule, I'd like to just share some of our (inaudible) concerns in five areas: the mandatory, not voluntary nature of the proposed record-keeping requirements, the increased burden, excessive cost and no identified benefits, the lack of necessity for the rule, the technical infeasibility of the proposed record-keeping requirements and some data security concerns.

Although EPA asserts in the preamble that the rule is voluntary, there is nothing voluntary about the record-keeping

provisions in this proposal. EPA is proposing for the first time that existing records which may meet EPA's broad definition of electronic records do not satisfy EPA's record-keeping requirement.

With this rule, EPA's introducing language that it would have very significant financial and compliance obligations for oil natural gas companies. The proposed rule would establish mandatory procedures and controls for all electronic records related to any data used for complying with the multitude of EPA reporting requirements. For example, in just the air area alone, the rule would apply to NSPS (phonetic) (inaudible) records, permeating reporting requirements on inspections, accidental release information, calibration data for (inaudible) control equipment, (inaudible) any readings, just to name a few, and it goes on.

The proposed rule states, an electronic record or electronic document will satisfy a record-keeping requirement of an EPA administered federal environmental program under this rule only if it's generated and maintained and find acceptable electronic record retention system as specified in the subsection. The definitions provided for an electronic record, and electronic record retention system, would capture any data or information stored on computers as well as the software, records, documentation, used to retain exact copies of

electronic records and documents.

In essence, EPA would no longer recognize electronic records unless computer systems satisfy the complex criteria set forth in the rule. EPA contends that the rule is purely voluntary, because companies have the option of paper record-keeping. However, many companies have already invested heavily in systems for electronic record-keeping. And the proposed rule would require extensive upgrades to existing systems, or may even necessitate entirely new systems to replace the existing systems.

The only place where the proposed rule would have no impact would be where the records were maintained in manual logs. In all other cases where the manual data were copied into electronic records such as Excel spreadsheets, mentioned earlier, or custom electronic management information systems, or entered directly from electronic logs to existing information systems, the implications of the rule are very significant.

Based on the definition for an acceptable electronic record retention system, any system that is used for complying with the environmental record-keeping requirement would be forced to comply with the record-keeping provisions of this rule. This is clearly not voluntary.

EPA must consider the reality that many companies have

already invested millions of dollars in computer hardware, software and support infrastructure for environmental compliance including record-keeping. Upgrading to meet the proposed standards would be very expensive and switching back to paper records is not a costless option. It is also contrary to the Paperwork Reduction Act. In some cases, it would be impossible to switch back to paper only system and still keep compliant records because some information is by nature computer generated. For example, for continuous submissions monitors, fugitive emissions data loggers, laboratory analytical equipment, temperature and flow meters, several states are already requiring that certain reports be submitted electronically.

Although we have not completed our calculations for potential costs for the oil and gas industry, an example of the excessive costs of the proposed rule, which was received from an API member company, is worth mentioning. This company has a robust emissions calculations program that can calculate all of their emissions and then use the results for determining chemical thresholds and emissions annual TRI report. It took 12 to 15 man years of effort to build this program and a cost of about two million dollars. This program is used at multiple facilities including five refineries, pipelines and marketing facilities. Modify this program, and time, date, user stamp

each data element, and to allow for storage and reasonable retrieval of this audit trail would require an extensive rewrite of an extremely complex software program. The company's IT contractor, who currently supports this program and assisted in building it in the first place has estimated it will take at least one man year to modify. The low-end costs for the modifications would be 200 to 250 thousand dollars. This cost is just for one program for one company.

In addition to this initial cost, the cost of data storage and software maintenance of this expanded program would increase significantly. In addition to fixing the audit of data element changes, it appears that the rule would also require a full audit trail of any and all software modifications along with a complete analysis of the effects of any results calculated and any software changes. If one is truly interested in auditing all data changes, this is just the cost. The company sees no benefit side to their organization, do not believe that they have a data problem that needs fixing.

The electronic record-keeping provisions would introduce significant costs to the oil and natural gas industry in the form of upgrading and/or replacing existing information systems that contain data required for environmental record-keeping, implementing new systems for tracking environmental records, revising an existing archiving backup and recovery practices to

address the extensive archiving requirements of CROMERRR.

Our analysis of the impacts of the proposal is in stark contrast to the analysis that EPA presents in the preamble. We believe that EPA needs to re-do its cost benefit and other analyses in order to meet requirements of executive order 12-8-66, Paperwork Reduction Act.

Now I might mention some things about the non-necessity. EPA claims the proposed rule would remove obstacles to electronic record-keeping. However, as practical manner it would do just the opposite. EPA has not identified the problem that they are trying to solve. EPA already has the necessary authority to examine paper, electronic records to ensure compliance. The record-keeping requirements are both unnecessarily broad and unnecessarily prescriptive. EPA has not adequately demonstrated the proposed electronic record-keeping requirements need to mirror that of the FDA electronic record-keeping regulations.

Consistency with FDA record-keeping requirements is not an appropriate goal. The FDA requirements have proven to be very difficult to implement and very expensive to the regulated community. Compliance with the FDA rule has proven to be so difficult that it's years behind schedule. The FDA experience should serve as a model for EPA, a model of what not to do.

If people want electronic recording, it can be

accomplished in a manner that is less costly and more efficient than paper record-keeping. Unfortunately, the proposed rule would have the opposite effect. Rather than encouraging electronic record-keeping, the rule would impose excessive cost that far outweigh the suggested benefit, thereby discouraging broad implementation. In many cases the effect of the rule would be a reversal in the progress companies have made in the area of electronic record-keeping.

Although EPA states for electronic reporting that it believes that technology specific provisions for reporting would be very complex and unwieldy; it then proceeds to propose just such provisions for electronic record-keeping. EPA needs to give further consideration to current record-keeping realities.

Electronic record-keeping is necessary for many practical purposes due to the complexities of records, calculations involved, transmission and storage of records. These electronic record-keeping systems vary among companies and over time. Due to the very nature of information technology, these variations can be expected to continue. Any EPA attempt to mandate computer system characteristics as the proposal does is doomed to fail. EPA's proposal reflects no awareness of the current state of computerized record-keeping in the regulated community. The specific system requirements EPA proposes range

from problematic to infeasible. In our written comments, we'll provide EPA with additional input and a technical aspect of the record-keeping.

The final area. Some aspects of data security and confidential business information concerns. As proposed, the rule appears to allow EPA overly broad access to corporate computer systems if records are retained electronically. The proposed rule requires that the electronic record retention system be readily available for "onsite inspection and offsite review for the entirety of the required period of record retention." Most industry facilities with data security and proprietary reasons do not maintain a system architecture that would allow EPA or other non-employees to get into the types of systems used for the clients record-keeping from offsite. Making these changes to comply with the proposed rule would jeopardize data security, and would impose additional cost.

EPA already has authority to obtain or inspect required records. There's no need for any expansion of this authority. The proposal appears to lay the groundwork for overly broad EPA access to entire computer systems. For the regulated community, this introduces a new level of concern about keeping business information confidential and may limit their ability to integrate environmental systems with other business systems. This should concern EPA as well because inspection or review

will not be facilitated. The companies would have to take extra steps to maintain confidentiality of their business records.

Conclusion: Due to the various problems already mentioned, EPA should withdraw the proposed rule. Any rule involving electronic reporting or record-keeping must involve computer experts, software companies and the regulated community. API is in the process of assessing the cost and operational implications and feasibility of various provisions of the proposed rules. We will be filing extensive comments in a few weeks. Thank you.

**Tom Gilding:** Yes, Tom Gilding of American Crop Protection Association. We've bounced around a lot this morning about voluntary, not voluntary. But the question that comes to my mind is specifically addressing the Office of Pesticide Programs (inaudible) submissions where the evolving program is (inaudible) CD ROMS and I think you've heard that they're also talking paper archiving. And I've also heard, David, you say this morning that such programs would be exempt from reporting from the CROMERRR. The logical question, which I haven't heard yet this morning is if such a approach is exempt from reporting, then would the record-keeping requirement also not apply? Would it apply?

**David Schwarz:** I think that's a question we'd have to think

about. I mean I don't think that ...

**Tom Gilding:** Very important to us.

**David Schwarz:** Oh sure, I ...

**Tom Gilding:** I mean I could go home right now if you say yes...

**David Schwarz:** I'm sure it is, but this issue of reporting and record-keeping are different. Because in the case of electronic reporting per se, we're not really interested in how you store the information that you report to us. But of course that's really what the record-keeping part of CROMERRR is all about. And there ...

**Tom Gilding:** Well you are saying then that an entity could be exempt from reporting but it still wouldn't be exempt from record-keeping?

**David Schwarz:** Yes, that's possible. I mean certainly as currently written.

**Tom Gilding:** When would we find this out?

**David Schwarz:** Well, as currently written, the proposal has the characteristic that you've just articulated. Yes, one could be subject to the record-keeping portion of CROMERRR but not to the reporting portion of CROMERRR now. Based on comments that we hear here, that we receive in writing, we'll obviously want to think long and hard about some of these issues. And I think that the answer to your question about what we will do will

depend on what we can do based on analysis.

**Chris Hartley:** Chris Hartley, DuPont. I have a comment and then a question. The technology costs and resource issues associated with archiving and electronic data for periods ranging greater than five years are enormous. One must consider the ever-accelerating rate of new technology to the market, the burden of maintaining CROMERRR compliance, the retirement of old technology, the loss of technology vendors and expertise match with the increasing costs for continued support migration of legacy systems.

My question is, given these barriers what plans does the agency have for reevaluating the value add associated with existing cost retention time weighted against the significant cost of maintaining records and the systems needed to read and analyze those records electronically for periods greater than five years?

**Evi Huffer:** We're well aware of the problems that are associated with maintaining records for long periods of time. We're basically pushing the envelope of technology in many cases. This isn't just an EPA problem. This is a universal problem. We are continuing to do research on the electronic records issues.

We are looking at emerging technologies that are coming onto the horizon. How we deal with it will probably be handled

on a program-by-program basis, and it will depend on the probably the level of risk associated with a particular record.

Valerie Vonetta: I'm Valerie Vonetta with the Alliance of Automobile Manufacturers. I just wanted to underscore our concern also with the record-keeping provisions and on the reporting side, the concern that there may be more than one person who would be involved in signing off on the data that's submitted and (inaudible) could be more complicated than one person. So the question that was raised earlier by DuPont is also relevant for us.

I also wanted to underscore that when you have 56 plants, they all have individual facilities that have had individual record-keeping and systems that have developed over time from different bases, so it is not always a simple matter of one patch for one technology for complying and it's going to be a lot more complex for each facility to analyze as more detail comes out about what the requirements are. Thanks.

**Mike Heyl:** My name is Mike Hile. I'm from Synthetic Organic Chemical Manufacturers Association (SOCMA). We just wanted to support the comments of Mr. Duvall from Dow, and just reiterate the point that many of the record-keeping burdens associated with the larger company, the loss would affect a smaller company. With that in mind, we're concerned that (inaudible) analysis was not conducted and that the rule has certified that

there would not be a significant impact on a substantial number of small companies.

We would urge the agency to review that and to rescind the rule, at least the record-keeping portion of it, to review these impacts. And due to the multi-industry impact that this is going to have on any industry that reports environmental information or may keep records to support that effort, enact the (inaudible) panel process (inaudible) enforcement in various acts. Thank you.

**Howard Kruger:** Howard Kruger, Proctor and Gamble. Since I've already made some of the points previously in my comments on reporting, I won't go in much detail on a few things. I will just reinforce that our company likewise sees the record-keeping issue as the most significant and we also conclude that it is definitely mandatory and not voluntary given the kinds of records that you have to keep and the current pervasiveness of the use of computers and the business of business systems in the United States of America.

I do want to just comment on a couple of things. And this is not meant as a complaint, but it is meant that to give you some insight into the challenge to try to understand the economic impact. First of all, the scope of CROMERRR is vast. And one of the things we tried to do is to try to just use EPA's own figures to do some calculations. So going directly

to the CROMERRR document itself, and using figures that were contained in the Federal Register, it's very difficult if not confusing actually impossible to recognize and reconcile.

First of all, find the figures and then reconcile them. In some instances, the agency has put economic impact numbers in terms of facilities. In some places it's listed in terms of respondents. In some cases it's listed in terms of registrants. And these all occur within the same paragraph and within adjacent paragraphs. So it's very difficult to say like, okay for facilities, here's the numbers, or respondents, here's the numbers.

But nevertheless, in an attempt to do some calculation on just the impact of record-keeping, we took the net average annual savings for all facilities, for implementing the reporting ... I'm talking about record-keeping but you're going to hear me use reporting because I'm trying to back out a number. The net average annual savings for all facilities for implementing the reporting, for implementing and reporting, electronic reporting was listed as 52.3 million. That's on page 46178. We divided that by the net average annual cost savings per facility, which is provided on page 46178, that being \$1,140. And that yielded a figure of 45,877 facilities. Again, I'm just trying to find, trying to calculate how many facilities were involved.

Now, although we believe there are many more facilities than this, just using that number, and multiplying it by the \$40,000 upfront cost per facility which is provided by the agency on page 46178, if you multiply 45,877 facilities by \$40,000, so cost per facility times facility, you come out with a cost by EPA's number for electronic record-keeping alone, not counting reporting, of 1.8 trillion. I mean seriously, just multiply the numbers.

Now regrettably, I'm skipping billions. Sometimes in my own company I won't allow people to use the word billion. I require a ... anytime someone says a billion, they have to say a thousand million, and every time they say trillion they have to do the same thing because it's easy to say 1.8 trillion. You say that's not so much. But you're using the 'T' word. You're bypassing billions and your upgrading from there, so this is a huge cost.

And as I made the comment before to this gentleman up at the table, this is actually real money that has to be found, identified and then spent, even though you may identify that there are some savings. Nevertheless, to accrue the savings, you have to actually get the money in the first place. So this is 1.8 trillion dollars just using your numbers. But it was very hard for me to try and go through here and really do a fair economic analysis because the numbers are all mixed and

confused.

And then I'd like to say just a little bit about the timetable issue again, realizing that CROMERRR is still in the proposal stage, we still have to sort of think about the eventual issue of implementation. And I would just say that the agency could benefit by talking with their sister agency, the FDA, regarding the implementation challenge that they have faced under 21 CFR Part 11.

As I made comment before to Joe, the rule was passed in March of '97 and made final in September of '97, so that's four years. I personally attended the audio conferences in May and June that the agency held this year. Each was a half day. And in those conferences, they were saying well we realize there's a serious problem here. We can't even get into compliance. But we will not hold you in non-compliance if you, number one, generate a master plan, which means identifying all the systems that your company has that needed to be compliant.

Number two, identify who the owners are and what the deficiency was -- so a gap analysis. And then number three, identify a time table that you believe that given the extreme cost that would be involved and the live bodies that would have to be found who know enough to actually make these changes, a time frame. And then they made this statement that we realize for large companies this could be very complex and it might

take three, five or even seven years. Now you can get the video, you can get the reports of this FDA conference.

I mean seven years. And we're still working on our master plan. We have it pretty well together, but if you add seven plus four, that's eleven years. So I just want to get across how long it takes.

And I think it has been made clear, the cost of some of these programs that, we don't believe they're out there. Now I'm impressed when someone found one of these that you can actually go out and buy, but because the companies have been working on them, they realize how valuable they are, and so they're going to charge an arm and a leg.

The final comment I'll make is on records integrity and validity. And I'm just going to read what I have here. One item, one final item deserves comment. There is a clear perception conveyed in the preamble of an underlying presumption by EPA that there is a problem with the integrity of information reported and records stored electronically. There seems to be a concern from the EPA about fraudulent records and records being changed without authorization.

Quite frankly, we're not aware of such practices and we, our company doesn't have these problems. But should EPA discover that there is some kind of a problem with electronic records, it has the authority to inspect the facility, audit

those appropriate records, and determine the reasons for discrepancy. And then where appropriate administer penalties.

As has always been true in the United States, there should be an exception and assumption that reported information and supporting records are accurate. And again EPA has the copy of the original record that they can measure against. A key point here is accuracy is not dependent on whether a record is held electronically or paper. If you're out to do change, you can change an electronic record as easily as you can a paper record, and therefore adopting extensive costly measures which are unique to individual electronic records is, to me, seems ill-advised and unjustified. So I would also like to second the comments that were made by Mr. Duvall and the gentleman from API.

I don't want to be redundant and feel like I'm dumping a lot of cold water on things that have already been said, but I think that they have been, the agency has been advised of problems that have been found and we have found these same problems.

Thank you.

**Kathleen Barrowclough:** Kathy Barrowclough, DuPont, representing SQA. We alluded to this this morning when talking about reporting. However, I'd like to get it in the record and get a response if possible around the record-keeping portion of

the rule, whereby in the preamble and in the rule you indicate, or EPA indicates that you will provide notice when you are now accepting electronic record-keeping. You say that same thing about record-keeping that you do about reporting.

What does that mean for the almost unanimous group of the regulated entity that is already keeping records electronically? I think this is the point we've tried to get across, that we're already keeping records electronically for all of the different environmental programs, not just the GLP program. And what, what do we have to do when CROMERRR is issued if we're already keeping records electronically? Do we have to wait for you to issue something in the Federal Register saying, now for X-Y-Z program we are accepting records electronically, or how is that applying across all the programs?

**Michael LeDesma:** The rule does not, and purposefully, does not speak to record-keeping that is currently ongoing. So whatever the status of that record-keeping is, the proposal and the final rule wouldn't change it. Now what the turn-on provisions that are described in the rule are intended ... I mean, to back step, what we're doing here is we're, we are with this rule creating omnibus requirements that we then intend to turn on with respect to certain programs (inaudible).

For example, with respect to CDX, we've got to prepare web

pages and things that need to go up. They'll need to be available for people to submit this information with the agency. And so the way the rule is structured, is that this rule will be finalized, will take effect, and then we will let people know that we've now finished the work involved in turning on a system that is ... they can go to our website or using the CDX process, go to our website and find the information there.

The same has to do, I mean, so the reporting provisions have the turn-on feature. The electronic record-keeping provisions, in my understanding, apply as soon as CROMERRR becomes effective. So there's a split there, as I understand it.

**David Schwarz:** Well, I think one of the issues that's been raised by the commentators is that the proposal makes assumptions about the prevalence of current electronic record-keeping, which may in fact be a mistake. It's something we've obviously got to consider. And part of the basis for that assumption was our understanding that many, although certainly not all, that many EPA record-keeping provisions or environmental regulations have references to paper that we had interpreted as precluding that kind of record-keeping.

On that assumption, the idea was that as CROMERRR was implemented, we would program by program, but rather the

programs themselves, when they felt that they were ready to conduct their compliance monitoring in an environment that involves electronic records, publishing those and saying we're ready. What we've been hearing this morning is that some of those assumptions may be mistaken. And correspondingly, I think we need to obviously consider that, whether that's true or that may affect the structure of this part of CROMERRR.

**Michael LeDesma:** (inaudible) program may not work (inaudible) electronic record-keeping in some cases, there may be some cases where CROMERRR says no I want a piece of paper with a signature on it as the record on the side. And so we didn't want to sort of globally say at this point that you have to keep a record for EPA automatically. It could be electronic because there were some programs who said, no wait a minute, there were some pieces of paper, some cases where we still want to have a piece of paper. So we wanted to give them the ability to continue to require paper in this (inaudible).

**Bill Barta:** Bill Barta, FMC Corporation. I have a couple of comments. There's, in quite a few places in the regulation it talks about exact copies. And I wasn't quite sure what that meant. I think I do, but I'd like to hear your version of that. And also I'd like to hear what you think the impact that would be on both the regulatory and the legal side. For example, 40 CFR 169.2, Part K, is books and records, which

requires the pesticide industry to maintain the originals of all documents. And I'd like to hear how you think that's going to be impacted by the rule.

And if in fact we do have to keep those originals; that means legacy systems, which are a problem. I just want to give a brief anecdote that I had last month where someone wanted to archive a 386 computer. And the reason he wanted to do that was he had a piece of software that, number one, he needed to have to have a PC that had a three and a half and a five and a quarter inch drive, but he also wanted to have a CPU of a certain speed because the software was designed to run on certain speed and the new computers would not run his software. So I asked our IT department how feasible this was, and they said well you can do that.

But you have to understand computers are instruments that have to be turned on periodically. If you put it in a closet for a year, and turn it on, it probably won't work. So I'd like to hear your comments about the exact records.

**David Schwarz:** Can you help us out maybe and give us a site or two where the exact copy phrase occurs just ...

**Bill Bartaff:** There's one mentioned in the definitions sections under electronic record, I believe. Yes.

**David Schwarz:** Well, I'm not sure where the question is going. The thing is, I'd ask again if maybe you can help us a little

bit more here. And maybe say a bit more about the kind of issue that's riding and how this term exact copies is used in the definition.

**Bill Barta:** The issue is I want to know if I have to keep and exact electronic version with all the meta data forever because if I migrate it, IT people tell me that the migrated version is not an original. It's a duplicate; it's a copy. And are the books and records people going to accept what the IT people call the duplicate as an original. It's a little legalistic, it's technical ...

**David Schwarz:** Right, no ...

**Bill Barta:** But I want to know if ...

**David Schwarz:** Well it's helpful, and I don't think I want to sit here and try to answer that question off the top of our head. I think it's a good issue to raise and I think we need to think a little harder about that. I hope that the answer to your question is no, not in that sense. But before I say that I'm going to consult with some of my colleagues ...

**Bill Barta:** Sure.

**David Schwarz:**... and make sure that actually works for them.

**Bill Barta:** It's a special case for the ag business.

**David Schwarz:** Okay. Thank you.

**Pat Wood:** I'm Pat Wood with Georgia Pacific again and I found this most interesting listening this morning and I appreciate

all the work that all of you have done and it strikes me that when I step back, a couple things strike me as a problem that we have. The rule itself, or the proposal, is not very big, but it is incredibly complex. And in fact I think that Howard Kruger said that there's something like 47 questions that you raise in the document that we're all sitting here not quite figuring out (inaudible) computers turned on forever more or the original copies or what do we do.

But nonetheless if I could just think about timing, and this has nothing to do, it's not your fault. I feel very sympathetic to the agency right now. You have a proposed rule that hit the Federal Register on August 31st, which is right before Labor Day when most of us were on vacation. Two weeks after that the world changed for all the us. Most people, when I try to talk about this to other businesses around town, people haven't read it. They aren't aware of it; they don't know what CROMERRR means. They think maybe, we don't make chrome; we don't have (inaudible) problems. This is funny but it's also very tragic, because what you really have, it seems to me that you've addressed three different things here.

First of all, the Central Data Exchange, which some of us, as Joe talked about some time ago, we're supportive of it. Those of us who have tried to do something about data quality issues in the agency see the idea of electronic reporting as

the right step forward. But something's happened to it in making that step forward. First of all, the Central Data Exchange is not understood even by the people here in these rooms. And this is the dedicated group of people who actually tried to read this proposal. The rest of the world doesn't know it exists.

Second, you then are talking about this is a voluntary proposal, but yet this morning I've heard you all say that yes indeed, you might not actually be electronically reporting but you would become subject to the record-keeping. And that is the essence of what worries all of us about it, that we're caught up in this, and the entire universe of the regulated population in this country is caught up in it, but I would say that not even one percent is aware of it.

And my suggestion is, what really needs to be done, is you need to (inaudible) the entire world and break it up into three parts and have a series of public meetings with both the regulated public and the states so that we can all understand what it is we're talking about before (inaudible). And I find particularly interesting the turn-on feature, because if I understand it, with my limit of understanding of the way this whole thing works, right now certain elements might not be subject to this. Even by your interpretation, but six months, a year, two years from now, there might suddenly be a decision

from one of the programs, and then because this would be a final rule, and people had not objected to it, just as we've seen with the pharmaceutical industry, we would find great gobs of the regulated community to be brought into this, having giving up their opportunity to comment because that would have occurred in the year 2001, correct?

I mean, that's my reading of what we've heard today. So I would urge that you take it back, split it up into three parts, and we go back and try hard to translate it in such a way that we can actually get everybody else educated (inaudible).

**Kathleen Barrowclough:** Kathy Barrowclough, DuPont. And I'd like to follow up with Bill Barta's question around exact copies. The definition for electronic record, as stated in the rule, is any combination of text, graphics, data, audio, pictorial or other information represented in digital form that is created, modified, maintained, archived, retrieved or distributed by a computer system. So I think we can see what we believe an electronic record is that's covered.

But then the other thing is, it defines an electronic record retention system means any set of apparatus, procedures, software, records or documentation used to retain exact electronic copies of electronic records and electronic documents. We have, and then your requirements for electronic records apply to electronic records in an electronic record

retention system. So if we only have electronic record retention systems that have exact copies but not the original raw data, okay... So if you think of the original data as not an exact copy, then really, do your electronic records that are in your data collection systems for original data not covered by CROMERRR? Is it only if you migrate it somewhere so that you've got an exact copy of it somewhere else in some other electronic data retention system?

We're not thinking that what was intended. We're thinking that you meant if you've got an electronic record retention system with your original raw data in it, you have to meet the electronic record requirements. But where we're talking about the scope of the rule, some of the people who I had talked to said well, maybe the scope isn't as broad as what you think. Maybe it's only if you migrate it somewhere based on this exact copy piece of the retention system.

Can you give us what your intention was there? Is it really, if you've got an electronic record, with original data in it, you're requiring, or you're suggesting that CROMERRR applies with those nine requirements.

**David Schwarz:** I think the intention is, yes to that. And it may be that the definition needs to be recrafted in some way.

Michael Penders: Hi, I'm Michael Penders. I'm the president of Environmental Protection International and I'm

working with the ACC (phonetic) on some issues regarding this rule. Let me say first the respect I have for those on the table for putting together this rule. And when I site section 3-2000, the criteria for acceptable electronic document receiving systems, I think that's a laudable effort in identifying the elements of what we may build into environmental security systems. And there's a lot of work going on in that area.

I submit, however, they really do not have a place in this rule, particularly from an enforcement and compliance perspective. I participated when I worked at EPA's Office of Enforcement and Compliance Assurance in the 1999 ELI (phonetic) form that's cited in this Federal Register notice. And at that time, I advocated moving forward with electronic reporting without respect to the record-keeping requirements that were just then being discussed in an initial stage. I thought that because they were admissible in court already, if there were evidence of fraud dating back to the time of the telegraph, that the agency should go forward with the existing electronic reporting regime that was in place at that time.

I still think after reviewing the proposed rule that the agency has much more to gain from an enforcement and compliance perspective in moving forward and keeping the barriers low to electronic reporting from the regulatory community to the

agency. There's a whole world of useful information that the agency can then use from enforcement and targeting perspective and indeed from an environmental security perspective, nationally and internationally, that now is very difficult to get at and work together because it's not in electronic form.

However, what I've heard here is that the costs and obstacles for moving forward with these elements at this time would present a substantial obstacle for companies in moving forward with electronic reporting. I don't think that is the intent of this rule and these elements. The intent of some of these elements as I read them were to ensure the integrity of the submission and the audit trail and other elements. I think there are other forms and that's evolving. We're actually working with some data companies to develop certain of these measures in the context of data systems, audit trails and electronic reporting. However, I think in the context of this rule that raises the level and imposed costs, and I don't think there is any corresponding enforcement and compliance benefit to setting these forth in this rule at this time.

Instead, as with all electronic records, they are admissible in court. And then, if there is a question as to the fraud or other aspects of it, you then go behind the submission and indeed even two years ago, I thought in a context of electronic reporting there is more in the issue of

reliability and what is submitted than some paper records currently being kept.

I don't think that this is a good vehicle to go beyond what is currently kept in terms of records, audit trail and reporting for paper records. This is not the vehicle to bootstrap these other elements, which may be critical to a facility, from an environmental security perspective, but I don't think are essential in going forward with the rule to encourage electronic reporting and particularly from an enforcement and compliance perspective at this time. I'll submit formal comments analyzing this in more detail.

**Howard Kruger:** This will be very brief; I'll make a few comments after lunch, but there was a suggestion, because so many of the things that have been said here have been 'can't do this,' 'we need to do this,' a lot of changes, there was a suggestion made by the gentleman from API and I think Ms. Wood made the same thing. And I think it's very productive and I don't want it to get lost. And that is, I think there's a benefit here in getting together a group of representatives from the regulated community, the agency, computer experts and software developers. Get those people together and then understand what the specific goals are very clearly, and then work out a feasible solution. I just didn't want that, because it was said right at the end of this gentleman's testimony, and

I thought it was a very powerful point.

**(LUNCH)**

**Evi Huffer:** Just a note. Your names will be part of the official transcript at today's meeting that will go into the docket, so you'll find the information there as well.

**Jim Steffel:** Yes, Jim Steffel, representing the NAICC, National Alliance of Independent Crop Consultants. And I just wanted to follow up on a few of the points this morning. Relative to cost and listening to these large organizations that report their sales in magnitudes of billions or hundreds of millions, we represent a group of contract researchers who actually generate the data that, the actual data that supports the field data that supports the missions.

And we have some very, very small members, some of our members that likely do an annual couple studies is \$10,000 a year. And a rough estimate, and we will try to fine-tune this a bit, but probably 80 to 90 percent of our members fall in the category of gross sales of \$50,000 to \$500,000 per year, which would certainly emphasize the impact of these additional costs. And definitely eliminate some of our, the feasibility of doing this work for some people.

One issue does come to play in our case, unlike many of the other people who are mandated by the location of their facilities, the ag industry is mandated to show geographic

diversity in their studies. So on the other side of the scale, it is important to have the small operators in certain remote locations that represent geographic areas of all types of production areas (inaudible). So this is a real, causes a problem in our group, that we're trying to deal with.

We generate raw data, which is transferred to the sponsors, but we also provide our own raw data in a sense, our support data, the environmental data and our facility data. So we would also come under the requirement to archive our own data, and there is some concern about the ramifications of CROMERRR in us transferring the raw data we collect for the sponsors, transferring that raw data, moving the raw data from our facilities to their systems. So these are just some of the issues that we will, I think in support of some of the things that have been said here this morning, we will try to comment further on.

**Charles Reese:** Hi, Charles Reese of BASF Corporation. I just wanted to make a clarification on my beginning statement about our system that we were developing. I say we may have spent four million dollars developing a system which we did develop under FIFRA, but based on our June 6, 2000 meeting that we had in Chicago with the agency, and we first learned of CROMERRR, we did have to change the scope of the development of that system which significantly increased the cost. Because we had

to add the audit trail functionality, the validation and so forth, to meet CROMERRR. And since CROMERRR wasn't out, we did this based on Part 11, which we understood that the agency was using as an example. Just that clarification.

**Charles Reese:** What I want to talk about now though is a couple of things. What was mentioned before about this one size fits all mentality to the electronic record that concerns us greatly is that if Title III is going to require everything under Title 40 to fit CROMERRR, you have different types of records that you have to be concerned with.

Certainly some records are very important, but others are lesser importance. An examples would be something such as a master schedule, which is required under Title 40, CFR Part 160, but is simply a list of the studies that the testing facility is running. Now where does it become important for this type of record to have an audit trail functionality, to have validation, to have forward mobility? And there really isn't any metadata, but I can tell you right now all the FIFRA, most all the FIFRA companies are using Excel. This is just a simple list.

But however, this is just one example, and there are many examples, you have SOPs, you have training records, you have the master schedule. So these are things that you may have electronically, you may choose to do electronically, but these

things aren't, they're required by Title 40 but they're not what we would consider a high level of priority for security. And so, but if CROMERRR applies, then it applies right now across the board in every level. So that's a concern.

One thing we had talked about, what Jim just said, a small business, small businesses, BASF is in the business of using contractors to do work for us. But these contractors could be using systems that are completely different than BASF systems. So if you have a contractor using a Platform A, and we've hired them but we use Platform B, how is it that we're supposed to transfer these records, or will the system be that we pay to maintain the records at the contract facility? These raise all kinds of questions and costs as to how to achieve those goals so we're in compliance.

One thing I wanted to get back to is the bottom line is, that companies are interested in, is compliance. How do we comply? We know there's going to be a rule; we know that we're going to have to comply with it. So what does that take? The reason I ask that is because there are some things in CROMERRR that we're interested in, but that CROMERRR doesn't really say anything about. One of those things is validation. We know we have to have it, and we agree we have to have it, but what is acceptable validation?

It shouldn't come down to, well you get your first audit

and you're not doing it right. So you need some sort of guidance there. June 6, 2000, I believe, Evie, you actually mentioned GLPs quite a bit, which have an example of validation. And now we've moved toward Part 11 as an example, so if we're going to go back and rework this electronic record-keeping then we have to take into account how to manage validation.

My last comment is, since GLPs, we also have a counterpart in the European side, the OECD. The OECD states that at the end of a, the end of the life of an electronic system, you have the ability to migrate to a different medium. Now they don't say what that medium is, but to a different medium. That would imply that if, once an electronic system has run its course, that a paper medium is acceptable if you can no longer move from one electronic platform to the next.

So is it possible when we re-look at this and rethink about it, that we could actually look at something, at least have an out, if your system is completely incompatible with the next technology ... You know, I always bring this up, but we have Pentiums now, but just around the corner is Iteniums. So, and a few other people had mentioned that platforms, running old software on new platforms just didn't work. So there is the opportunity here to have a legal out, where you can print out these things, like the OECDs give us, so we can manage this

a little better.

**Evi Huffer:** What document or guidance are those OECD provisions under?

**Charles Reese:** Yes, it's a consensus document. Yeah. I can (inaudible)...

**Evi Huffer:** (inaudible)

**Charles Reese:** Yes, I can get that to you, Evie.

**Evi Huffer:** If you could, that would be great.

**Charles Reese:** Okay.

**Evi Huffer:** Thank you.

**Charles Reese:** Thank you.

**David Schwarz:** If you or any of the other commenters have a principled way to distinguish between records that need a high degree of security and those that maybe don't, we would be very interested in those proposals.

**Jamie Conrad:** Thanks. I'm Jamie Conrad; I'm with the American Chemistry Council. I don't have a statement but I did have some questions I thought I would just ask, and maybe some suggestions that could come along with them. In developing this rule, have you all sort of taken kind of an inventory of EPA's own record-keeping requirements in terms of which ones either mandate or allow, explicitly allow electronic record-keeping versus those that are silent on the topic, versus those that say they must be paper?

**David Schwarz:** We did a sort of partial inventory. We did a search of our requirements to see where certain keywords came up that seemed to suggest paper. And we got tens of thousands of hits, and that was enough to explain to us that, given our timetable, going through the CFR and trying to tease out each of these was simply beyond the scope of our resources. But it also persuaded us that, at least in terms of addressing the removal of those kinds of obstacles to record-keeping , we really needed a sweeping approach, rather than amending the CFR provision by provision. So we did some things in that direction, but not a complete analysis.

**Jamie Conrad:** Because I've seen someone who did a keyword search of computer, through 40 CFR, just the air ones and the list goes on like this. We can I think forward that to you, but there's quite a lot of them. I also said, I think in a meeting once, that we had compiled all these record-keeping requirements. Had we given you this at the last meeting?

**David Schwarz:** No.

Jamie Conrad: Here it is. It leaves out FIFRA, unfortunately, but it's, the pagination's messed up. It's 208 pages  
(inaudible)

**Female Participant:** (inaudible)

Jamie Conrad: Well there won't be an audit trail.

**David Schwarz:** It's all right. It's only a proposed rule.

**Jamie Conrad:** How about ... I guess a related question is, have you done any looking into how regulated entities that keep records, whether they use paper or computers or at what point in the process they use computers?

**Evi Huffer:** We're doing that research right now. Again, based on our early analysis, it did not look like electronic record-keeping was that widespread across the industry. When you talk about the programs where electronic record-keeping is allowed, we basically know the good laboratory programs, the acid rain program, reformulated gas. And then there are the other programs that do mag media electronic reporting.

**Jamie Conrad:** Well, I suppose that (inaudible) comments will be illustrating many of the instances where electronics ...

**Evi Huffer:** And again, where you can give us specific examples where you're using electronic record-keeping, for what particular programs, that would be very useful.

**David Schwarz:** I just feel I need to add to that. As you know, we did hold two public meetings on the rule substantially before the proposal. I think they were in the spring and early summer of 2000. And we had hoped that companies that in fact were doing electronic record-keeping would make themselves known and that we'd service those kinds of concerns early. But we really did not get very many comments that suggested to us that this was an ongoing activity.

**Jamie Conrad:** I actually went to that meeting, the one July 11, 2000, and I have the original paper copy of the handouts that were in my notes. And this is my note up at the top with an asterisk: people are freaked about not being able to print out computer documents and sign them.

Few people have or can afford all the electronic audit trail stuff to ensure no changes. So I heard, I mean, people saying FIFRA reporting may not be operative but the FIFRA record-keeping rules might apply if you keep records electronically. So there were plenty of people who referenced the FDA rule and FIFRA at that meeting.

**Evi Huffer:** Again, most of those folks were companies that were subject to the automatic Good Laboratory Practices under the FDA program. It's basically a group of industry that commented largely at those meetings and they were largely the FIFRA labs (inaudible) ...

**Jamie Conrad:** Yes, but I guess it seems though (inaudible). Where folks are keeping records electronically, do you believe that the Government Paperwork Elimination Act requires anything, EPA to do anything? Say for example, under NESHAP where people are keeping electronic data on air missions.

**Michael LeDesma:** The question is does the Government Paperwork Elimination Act compel EPA to (inaudible) ...

**Jamie Conrad:** Compel EPA to do anything about those instances

where electronic record-keeping is going on and no one seems to be unhappy with it, or preventing it, or no one's denying these records' legal validity or that sort of thing.

**Michael LeDesma:** If I recall correctly, EPA required that we make an option of electronic reporting and record-keeping available where practical. (inaudible) to make that available across the board (inaudible)

**Jamie Conrad:** So how would that relate to what's going on now?

**Evi Huffer:** I think that, is your point the fact that you're claiming that widespread electronic record-keeping is already going on in various programs across the board.

**Jamie Conrad:** I'm thinking if GPEA says that agencies should make electronic reporting available where that's a practical option, and that they should ensure that electronic records aren't denied legal validity and enforceability and so on. If in fact that's what seems to be occurring, then one interpretation of the GPEA no obligations on EPA to do anything further. It's only in those instances where the word paper is used in the regulation that creates an obstacle. The GPEA would say you've got to take that, you know, paper word out of the regulations, but that otherwise, if it ain't broke don't fix it.

**Michael LeDesma:** Well, I mean, unless industry stands up as a whole and says we want you to declare to us that our current

record-keeping, electronic record-keeping report, well, record-keeping is illegal, the agency is not proposing to do that. The agency is proposing that whatever the current status is, we're going to .... GPEA requires that we define how that electronic reporting is going to take place, and how that electronic record-keeping is going to take place in the future. But I don't think, through GPEA, I mean through CROMERRR, we're trying, we're attempting to speak to the past.

**Jamie Conrad:** But the, I mean there is, I went back and checked after you raised the question, issue earlier. GPEA does say that electronic record-keeping once, I'm sorry that the CROMERRR, once CROMERRR becomes effective, it says that there can only be electronic record-keeping where it's been turned on. The turn-on thing is in both reporting and record-keeping. Which would suggest that all current electronic record-keeping practices would be illegal once CROMERRR becomes effective, unless those are not electronic records somehow.

**David Schwarz:** I think we talked a little bit about that this morning. That wasn't the intent. And if it turns out that that is in fact the effect, then we need to reconsider that.

**Jamie Conrad:** Okay. I guess my last question is, did EPA ever conduct the risk analysis that's discussed in the OMB's GPEA guidance talks about doing a risk analysis of the likelihood of fraud and the potential degree of harm if there was fraud

versus the costs in terms of money and operability and the kinds of remedies that might prevent that.

**Male Participant/EPA:** Where our primary focus on the risk analysis is (inaudible) wide range of (inaudible) from the record-keeping (inaudible)

**Jamie Conrad:** Is there a document in the docket somewhere that represents that risk analysis?

**Male Participant/EPA:** I believe that there (inaudible) I'm not really sure.

**Evi Huffer:** GPEA (inaudible)

**Jamie Conrad:** Is it something you'd be willing to put in the docket, or is it (inaudible)?

**Evi Huffer:** (inaudible)

**Jamie Conrad:** Okay, thanks.

**Mark Duvall:** I'm Mark Duvall with the Dow Chemical Company. I wanted to follow up on Howard Kruger's comment about the cost and the arithmetic that he did. I'd like to offer a different view.

According to the EPA cost benefit analysis, there are 1.2 million facilities with EPA reporting obligations, either reporting to EPA itself or to states and tribes and so forth. It seems reasonable to assume that if there are 1.2 million reporting facilities, there are at least that many facilities subject to EPA and related record-keeping facilities, record-

keeping requirements.

So if we use for working purposes 1.2 million as the number of facilities which have record-keeping obligations, and if we assume that all of them use computers in keeping at least some of those records at least some of the time, then that's the number that we would multiply by whatever the cost of the record-keeping provisions would be.

So if we take EPA's cost benefit analysis figures of \$40,000 for an initial cost plus continuing costs, if we just focus on the \$40,000 and multiply that by 1.2 million facilities, it comes to a total of \$48 billion, just for the record-keeping piece, just for the initial investment. My question is, in EPA's evaluation of the rule, have you done any justification for a number on that order of magnitude for costs?

**David Schwarz:** I think the question really goes ultimately to this question about whether or not the rule is voluntary. From our perspective, at the time we were writing this rule, we understood that this rule was voluntary.

And in fact, I mean as a legal matter it is voluntary. With limited exception, very limited exception, electronic record-keeping is still voluntary. So, I mean I guess the issue is really, the question that you're asking really goes to the question of whether or not it's voluntary, and the agency's

again taking a look at that.

**Mark Duvall:** Thank you.

**Kathleen Barrowclough:** I haven't got this one written down ahead of time so I may stumble a little bit. Kathy Barrowclough, DuPont. And when you're talking about electronic document receiving systems, EPA puts certain criteria associated with an electronic document receiving system; these are over and above electronic record-keeping requirements. You've only indicated nine electronic record-keeping requirements. And then you also distinguish between and electronic record and an electronic document, indicating that an electronic document is one that is transmitted over the wires.

And there are specific requirements for electronic documents that are also not applied to electronic records. When we look at all of those different requirements, we see an opportunity to apply any of those to electronic records, and we would just like to, I guess, hear clarification from you in that the requirements for electronic document receiving systems, which are a robustness that we would associate with our electronic record-keeping systems, our data collection systems.

But you're not applying those to electronic record-keeping systems. Nor are you, there are some particular things around

electronic signatures, in the electronic document requirements. You are not also applying those to electronic record-keeping is what it appears in the rule. And I just want a clarification from EPA on that.

**Male Participant/EPA:** Yes, and again I guess we will have to make sure that this is absolutely clear in the final rule, but the criteria for what we call electronic document receiving systems are meant to apply to systems created and maintained by state or local agencies that operate a localized program (inaudible) allegation.

They are not meant to apply to companies that are regulated by EPA or by these state or local agencies. So in this completely different universe of entities that are being addressed by these criteria for document receiving systems. Paul Toll: I'm Paul Toll with Bayer Corporation. And just to kind of second everything that's already been said today from the other companies, I was wondering since there are so many questions, so many uncertainties, so many things that you said you had to clarify, would you consider clarifying those and then open it up for another public commentary?

**Male Participant/EPA:** (inaudible)

**Kathleen Barrowclough:** Since we seem to be getting down to the end of the line here, Kathy Barrowclough, DuPont. And what I'd like to do is go back, several people have mentioned about

getting a group of the right people, stakeholders together, in some sort of a working group. And it's one of the things that the GLP community has encouraged over the past year.

We know we'd like to participate as well as probably several of the other interested stakeholders who are here. And I guess we're just wanting to hear something from EPA about how and when something like that might go forward other than just this public meeting forum, but a working group kind of meeting.

**Evi Huffer:** This is something that EPA can take back and consider, but right now we do not have any plans for such, performing such a working group at this time.

**Joe Retzer:** (inaudible) public comment (inaudible) get the comments in (inaudible) a good suggestion (inaudible)

**Michael LeDesma:** I guess just one other point about that, and that's why I kind of turned the mike. If we had such a group in conjunction with the rule making, it would probably need to be constituted under something called a federal advisory (inaudible) ...

**Evi Huffer:** Thank you very much.

**David Schwarz:** Thank you for coming.

**(ADJOURN)**